DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



## **Center for Beneficiary Choices**

**Date:** July 20, 2006

**To:** All Part D Plan Sponsors

**From:** Abby L. Block, Director

Center for Beneficiary Choices

**Subject:** Modified Q&A Addressing Drug Costs Reported on Prescription Drug Events

(PDEs)

On June 22, 2006, CMS released a modified Q&A specifically addressing how Part D Sponsors should report drug costs for plan year 2006, in light of guidance released on May 19, 2006. The guidance, as revised on June 22, permits Part D Sponsors to continue with current operations for 2006. However, CMS is expanding this guidance to plan year 2007 in order to further minimize disruption to plan operations and the provision of drug coverage to Medicare beneficiaries. Therefore, for plan years 2006 and 2007, Part D Sponsors who use the amount paid under the lock-in (or price risk) model as the basis for calculating drug costs will not be required to restate costs or change their operations. For plan year 2007 as in 2006, a Part D Sponsor that uses a PBM may use either the lock-in amount or the pass-through amount as the basis for calculating beneficiary cost sharing and gross covered drug costs throughout the benefit, as well as reporting drug costs on EOBs and PDE records.

However, the Part D Sponsor must choose only one approach and cannot switch between them for purposes of calculating cost-sharing and reporting drug costs. Thus, for example, if a Part D Sponsor has chosen the lock-in approach, the lock-in price must also be the basis for calculating what the enrollee pays while in the deductible or coverage gap. More specifically, regardless of which approach Part D Sponsors choose, they must use a consistent basis for: (i) calculating beneficiary cost sharing; (ii) accumulating gross covered drug costs; (iii) calculating TrOOP; (iv) reporting drug costs on the Prescription

<sup>&</sup>lt;sup>1</sup> In 2006, CMS required Part D sponsors to submit bids no later than June 6, 2005. However, Part D sponsors did not complete contracting with their pharmacy networks until after the bids were due. As a result, some Part D sponsors contracted with PBMs for a fixed price for their bids in 2006, not knowing the actual contracted rate with pharmacies until later that year. Some plans continued with this method of contracting for 2007. These Part D sponsors developed their plan year 2007 bids using the same lock-in model used for 2006, while others modified their bids to reflect the pass through model in time for the June 5, 2006 bid submission deadline.

Drug Event (PDE) records, and (v) developing bids submitted to CMS. This ensures that the beneficiary cost sharing and reinsurance payments received by the Part D Sponsor are consistent with the Sponsor's bidding assumptions.

In order to ensure transparency in bid development, we are now further clarifying that for plan years 2006 and 2007 all plans will be required to submit an actuarial attestation, through HPMS and hardcopy, which identifies the pricing approach (lock-in or pass-through) that was used in the development of the 2006 and 2007 bids. Additional guidance related to how plans may obtain the bid attestation will be issued shortly.

The June 22<sup>nd</sup> guidance noted that the deadline for submission of bid modifications for 2007 had been extended. CMS expects that Part D Sponsors will not need to amend their bids for contract year 2007 since whichever method of determining drug price amounts was used to develop the 2007 bid (i.e., lock-in or pass-through) is now considered appropriate for 2007. CMS intends to issue a Notice of Proposed Rulemaking to complete the transition to a single approach to contracting. Specifically, we will propose that the pass through model be the only acceptable methodology for 2008 and beyond. Therefore, Part D Sponsors who are currently using the pass through model are particularly encouraged to maintain their current bids as this will be the method of determining drug price amounts proposed for plan year 2008 and beyond. However, Part D Sponsors that would like to amend their bids must e-mail their requests to actuarial-bids@cms.hhs.gov by Monday, July 24<sup>th</sup> at Noon EDT. If a request is submitted, it must include the following items:

- 1) A summary of how this revised CMS policy for 2007 changes the assumptions on which the original bid was based and the method for establishing drug price amounts that will be used in the revised bids.
- 2) A sample revised bid pricing tool for a representative plan for which resubmission approval is being sought.
- 3) Identification of all of the plans for which the organization would like to amend the bid to reflect the revised CMS policy on drug price amounts.

To the extent that sufficient documentation is provided, organizations will be notified that they have an opportunity to submit an amended bid, which must be received by Thursday, July 27<sup>th</sup> at 11:59 p.m. EDT.

The only permissible change in the bid development is with respect to the allocation of any PBM gain/loss margin included in drug price amounts paid to the PBM between gross covered prescription drug costs and administrative expenses. This guidance only provides an option to reallocate this PBM gain/loss margin; all other components of administrative expense must continue to be accounted for as non-pharmacy expense. The total costs underlying the bid (for pharmacy expense plus administrative expense plus gain/loss margin) may not change, just the cost allocation. While the bid amendments may result in higher or lower overall bids, due to the impact of the cost reallocation on average enrollee cost-sharing amounts, the amendments may not assume any changes in PBM negotiation outcomes or other bid factors after the June 5<sup>th</sup> bid submission deadline. The cost reallocation must be reasonably related to the change in method for determining

drug price amounts, and a description of this relationship must be included with the summary described above.

The May 19<sup>th</sup> Q&A is superseded by this guidance.

## **Further Information**

If you have questions, or if you believe that the particular circumstances of your plan are not addressed by this guidance, please contact Meghan Elrington at (410) 786-8675.